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Clinical Paper
TMJ Disorders

Total alloplastic temporomandibular joint reconstruction using Biomet stock prostheses: the University of Florida experience☆

R. Sanovich[a], U. Mehta[a], S.Abramowicz[b], C. Widmer[c], M. F.Dolwick[a,*]

[a]Department of Oral and Maxillofacial Surgery, University of Florida, Gainesville, FL, USA; [b]Division of Oral and Maxillofacial Surgery, Emory University School of Medicine and Children's Healthcare of Atlanta, Atlanta, GA, USA; [c]Division of Facial Pain, Departments of Orthodontics and Neuroscience, University of Florida, Gainesville, FL, USA

R. Sanovich: Total alloplastic temporomandibular joint reconstruction using Biomet stock prostheses: the University of Florida experience. Int. J. Oral Maxillofac. Surg. 2014; 43: 1091–1095.

Abstract. The purpose of this study was to report the subjective and objective outcomes of temporomandibular joint (TMJ) replacement with Biomet stock prostheses at a single institution in Florida. In this retrospective study, patients who underwent TMJ replacement using a Biomet stock prosthesis from 2005 to 2012 were analyzed. Subjective (pain, diet) and objective (maximal incisal opening) information was obtained. In addition, a quality of life measure was obtained pre- and postoperatively. Significance was set at <0.01. Thirty-six patients (26 bilateral, 6 left, and 4 right) who underwent TMJ replacement using a Biomet stock prosthesis were eligible for the study. Maximal incisal opening improved from 26.1 mm preoperatively to a mean of 34.4 mm postoperatively. The pain score decreased from 7.9 preoperatively to a mean of 3.8 postoperatively. Diet restriction decreased from 6.8 preoperatively to a mean of 3.5 postoperatively. Quality of life improved from a median of 4 preoperatively to a postoperative median of 2. Four implants were removed/replaced because of heterotopic bone formation, infection, and/or loose hardware. Follow-up ranged from 6 to 83 months. Overall, TMJ reconstruction using the Biomet stock joint is effective and safe in this patient population.

Keywords: total joint prosthesis; temporomandibular joint; biomet.

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Indications for temporomandibular joint (TMJ) reconstruction include bony ankylosis, degenerated or resorbed joints resulting in severe anatomic discrepancies, failed previous alloplastic and/or autogenous joint replacement, severe inflammatory joint disease that has failed conservative measures, post-traumatic

condylar injury, post-tumour reconstruction, and developmental abnormalities.[1–3] The current recommendation for TMJ reconstruction of a skeletally mature patient is an alloplastic total TMJ replacement. The advantages of alloplastic TMJ reconstruction include immediate function, lack of a second surgical site, correction of skeletal deformity and malocclusion, and improved predictability.[1]

Currently, there are three TMJ replacement systems approved by the US Food and Drug Administration (FDA): (1) TMJ Concepts Prosthesis (TMJ Concepts, Inc., Ventura, CA, USA), (2) Biomet Microfixation TMJ Replacement System (Biomet Microfixation Inc., Jacksonville, FL, USA), and (3) Christensen TMJ System (TMJ Medical, Salt Lake City, UT, USA). In the oral and maxillofacial surgery literature, studies have shown that to date, the expected lifespan of alloplastic joint replacement is almost 20 years.[1,4]

The Biomet system consists of mandibular and fossa stock prostheses. The mandibular component is made from cobalt–chromium–molybdenum with a titanium alloy coating. It is available in three lengths (45, 50, and 55 mm) and three styles (standard, narrow, and offset). The fossa component is made from ultra-high molecular weight polyethylene. The screw system is made of titanium alloy. The fossa is offered in three sizes (small, medium, and large). The different sizes refer to the attachments; the condylar head and the fossa are the same size, regardless of the size of the component. The fossa component is attached to the zygomatic arch with self-tapping screws of 2.0 mm in diameter; the mandibular component is attached to the mandibular ramus with self-tapping screws of 2.7 mm in diameter.

The purpose of this study was to report the subjective and objective outcomes of patients with the Biomet Microfixation TMJ Replacement System at the study institution in Florida. It is our objective to add evidence that the stock prosthesis is biocompatible and effective.

Patients and methods

This was a retrospective cohort study of patients who underwent a TMJ total joint replacement at the study institution in Gainesville, Florida from 2005 to 2012. Subjects were included if they had a total joint reconstruction with the Biomet TMJ replacement system done by the senior author (MFD). Patients were excluded if: (1) follow-up was inadequate, (2) medical records were incomplete, (3) they had medical conditions not allowing for examination, or (4) they underwent other concomitant non-TMJ-related procedures (i.e., orthognathic surgery).

TMJ replacement was done in accordance with previously published reports.[2,5–7] Medical information and imaging studies were reviewed. Demographic data (gender, age) and diagnosis information (reason for the procedure) were recorded. Subjective variables included: (1) TMJ pain (pre- and postoperative; 1–10, 1 = no pain, 10 = worst pain), and (2) diet (pre- and postoperative; 1–10, 1 = regular diet, 10 = liquids only). Objective variables included maximal incisal opening (MIO; pre- and postoperative, recorded using a metric ruler in millimetres). Visual analogue scales (VAS) were used to evaluate pain levels and interference with eating. Patients were also questioned about their overall quality of their life, ranging from excellent (score 4) to poor (score 1), and whether, in hindsight, they would again choose to have surgery.

Descriptive statistics were calculated as appropriate for the data type. Paired *t*-tests were calculated to assess statistically significant differences between preoperative and postoperative pain and MIO outcomes using an adjusted probability value of $P < 0.01$ for multiple comparisons. The pre- and postoperative quality of life measures were evaluated by Wilcoxon matched-pairs signed-rank test (significance $P < 0.01$).

Results

From 2005 to 2012, 62 patients (106 joints) had a TMJ replacement. Of these, 36 patients (26 bilateral, 6 left, and 4 right) were eligible for the study. All patients were female, with an average age of 49.4 ± 11.9 years at the time of surgery. The average number of prior operations was 3.4 ± 2.3. Preoperative diagnoses included degenerative joint disease ($n = 15$), fibrous and bony ankylosis ($n = 7$), previous failed TMJ prosthesis ($n = 6$), rheumatoid arthritis ($n = 4$), trauma resulting in fractures ($n = 3$), and pathology ($n = 1$). Patients were in Wilkes class I ($n = 1$, 3%), class II ($n = 2$, 6%), class III ($n = 3$, 8%), class IV ($n = 8$, 22%), or class V ($n = 22$, 61%). The mean follow-up was 30 months (range 6–83 months) from the time of implant placement to the time of questionnaire.

There was an increase in postoperative MIO. The mean preoperative MIO was 26.1 mm (standard deviation (SD) ± 8.0 mm; 95% confidence interval (CI) 23.4–28.7), and at follow-up, mean MIO was 34.4 mm (SD ± 6.1 mm; 95% CI 32.3–36.4). The increase in mean MIO was greater than 8 mm and was statistically significant ($P < 0.01$; Fig. 1).

The mean preoperative restriction with eating was 6.8 (SD ± 1.7; 95% CI 6.2–7.3), while at follow-up, the postoperative mean was 3.5 (SD ± 1.8; 95% CI 2.9–4.1). This difference represents a statistically significant improvement in jaw function ($P < 0.01$; Fig. 2). A decrease in pain levels was also found. The mean

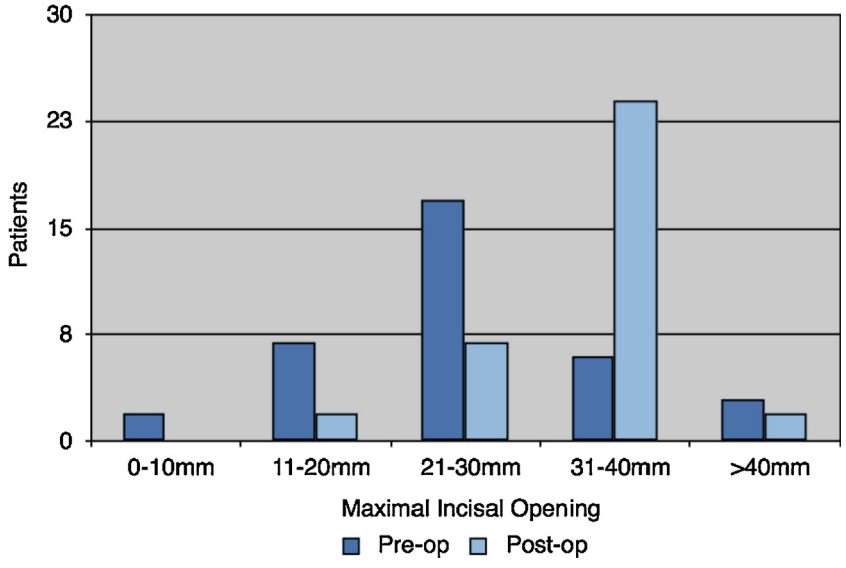

Fig. 1. Histogram depicting the distribution of the preoperative and postoperative maximal incisal opening (mm).